

August 6, 2001

Mr. Ronald A. Milner, Chief Operating Officer
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION'S OBSERVATION AUDIT
REPORT NO. OAR-01-06, "OBSERVATION AUDIT OF THE OFFICE OF
CIVILIAN RADIOACTIVE WASTE MANAGEMENT, OFFICE OF QUALITY
ASSURANCE, AUDIT NO. BSC-ARC-01-10 OF THE BECHTEL SAIC
COMPANY, LLC"

Dear Mr. Milner:

Enclosed is the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report (No. OAR-01-06), of the U.S. Department of Energy's (DOE's), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), audit of the Bechtel SAIC Company, LLC (BSC). OQA conducted a two-part audit of BSC on June 11 through 20, 2001. The OQA audit team (audit team) conducted the first part of the audit on June 11 through 15, 2001, at four national laboratories supporting BSC: Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, Los Alamos National Laboratory, and Sandia National Laboratories. The audit team conducted the second part of the audit on June 18 through 20, 2001, at BSC's facility at Las Vegas, Nevada. NRC observed the second part of the audit.

The audit team performed a limited-scope compliance-based quality assurance (QA) audit to evaluate BSC's implementation of the applicable provisions of the OCRWM Quality Requirements and Description (QARD) document, DOE/RW-0333P, Revision 10, and associated implementing procedures. During the audit, the audit team assessed the adequacy and effectiveness of the QARD procedures and verified compliance with requirements in the areas reviewed.

The NRC observers (observers) determined that DOE's audit of BSC was effective in identifying potential deficiencies and recommending improvements for the documentation and QA procedures reviewed. During the conduct of the audit, both the audit team and the observers independently reviewed applicable QA procedures, analysis reports, models, and software documentation. The observers did not submit any audit observer inquiries requesting clarification and information on audited documents.

Although the audit team identified potential deficiencies, the observers believe that BSC's implementation of the QARD, in the areas reviewed, during the audit was generally acceptable. The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit.

A written response to this letter and the enclosed report is not required; however, we do request that you respond to the open Audit Observer Inquiries from the previous observations identified in Section 5.2 of the enclosed report. If you have any questions, please contact Thomas Matula at (301) 415-6602.

Sincerely,

/RA/

C. William Reamer, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report
No. OAR-01-06, "Observation Audit
of the Office of Civilian Radioactive
Waste Management, Office of Quality
Assurance, Audit No. BSC-ARC-01-10,
of the Bechtel SAIC Company, LLC"

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Letter to R.A. Milner from C.W. Reamer dated _____ August 6, 2001 _____

cc:

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I. Zabarte, W.S.N.C.	

U.S. NUCLEAR REGULATORY COMMISSION
INPUT FOR THE OBSERVATION AUDIT REPORT NO. OAR-01-06,
“OBSERVATION AUDIT OF THE OFFICE OF
CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE
AUDIT NO. BSC-ARC-01-10
BECHTEL SAIC COMPANY, LLC”

 /RA/ 07/25/01
Thomas Matula
Projects and Engineering Section
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 /RA 07/24/01
Robert Latta
Repository Site Section
High-Level Waste Branch
Division of Waste Management

Reviewed and Approved by:

 /RA/ 08/05/01
N. King Stablein, Chief
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

Enclosure

1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management observed the U.S. Department of Energy's (DOE's), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), audit of the Bechtel SAIC Company, LLC (BSC). BSC is DOE's Management and Operating contractor. OQA conducted this two-part audit on June 11 through 20, 2001. The OQA audit team (audit team) conducted the first part of the audit on June 11 through 15, 2001, at four national laboratories supporting BSC: Lawrence Berkeley National Laboratory (LBNL), Berkeley, California; Lawrence Livermore National Laboratory (LLNL), Livermore, California; Los Alamos National Laboratory (LANL), Los Alamos, New Mexico; and Sandia National Laboratories (SNL), Albuquerque, New Mexico. The audit team conducted the second part of the audit on June 18 through 20, 2001, at the BSC facilities at Las Vegas, Nevada. NRC observed the second part of the audit.

The OQA audit team (audit team) performed a limited-scope compliance-based quality assurance (QA) audit to evaluate BSC's implementation of the OCRWM Quality Requirements and Description (QARD) document, DOE/RW-0333P, Revision 10, and BSC's compliance with associated implementing procedures in the following areas:

- Section 12.0 "Control of Measuring and Test Equipment"
- Section 15.0 "Nonconformances"
- Supplement I "Software"
- Supplement III "Scientific Investigation"
- Supplement V "Control of the Electronic Management of Data"

The objectives of the audit were to assess the adequacy and effectiveness of the QARD procedures and to verify BSC's, LBNL's, LLNL's, LANL's, and SNL's compliance with requirements in the areas reviewed. The objective of the NRC observation was to assess whether BSC had properly implemented the provisions contained in the QARD and the requirements contained in Subpart G, "Quality Assurance," to Part 60 of Title 10 of the U.S. Code of Federal Regulations.

This report addresses the NRC observers' (observers') determination of the effectiveness of the OQA audit, and whether BSC implemented adequate QARD controls.

2.0 MANAGEMENT SUMMARY

The observers determined that OQA Audit BSC-ARC-01-10 was effective in determining the level of compliance of evaluated BSC QA activities with the QARD and associated implementing procedures. The audit team identified six conditions adverse to quality that were documented as potential deficiencies. The observers agreed with the audit team's conclusions, findings, and recommendations. The observers found that the audit team members were qualified, independent of the activities that they reviewed, and knowledgeable of the QA requirements and the technical disciplines in the areas in which they performed assessments. The observers agreed with the audit team's conclusion that the OCRWM QA program had been satisfactorily implemented, except for the identified potential deficiencies.

3.0 AUDIT PARTICIPANTS

3.1 Observers

Thomas Matula	Observer	NRC
Robert Latta	Observer	NRC

3.2 Audit Team

John Doyle	Audit Team Leader	OQA/Navarro Quality Services (NQS)
Samuel Archuleta	Auditor	OQA/NQS
Patrick Auer	Auditor	OQA/NQS
George Harper	Auditor	OQA/NQS
Dennis Threatt	Auditor	OQA/NQS
Chet Wright	Auditor	OQA/NQS

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

OQA conducted this audit of BSC in accordance with OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program," and QAP 16.1Q, "Performance/Deficiency Reporting." NRC observed this audit based on NRC Manual Chapter 2410, "Conduct of Observation Audits," dated July 12, 2000.

4.1 Scope of the Audit

The audit team conducted a limited-scope compliance-based audit of activities and processes related to BSC's implementation of the QARD. Audit activities included evaluation of the control of measuring and test equipment, nonconformances, software, scientific investigations, and control of the electronic management of data.

4.2 Conduct and Timing of the Audit

The observers determined that the audit was performed effectively and that the audit team demonstrated an understanding of the applicable DOE and BSC programs and procedures. The observers also determined that the audit team members conducted thorough interviews, that they challenged responses, when appropriate, and that they effectively used their detailed audit checklist. The observers concluded that the timing of the audit was appropriate for the audit team to evaluate ongoing BSC activities. The audit team and the observers caucused at the end of each day. The audit team held daily meetings with BSC management (with the observers present) to discuss the current audit status and the preliminary audit findings.

4.3 Audit Team Qualification and Independence

The observers reviewed the qualifications of the audit team members for accuracy and completeness in accordance with the requirements of Procedure QAP 18.1, "Auditor Qualification." The observers also examined the levels of training, education, and experience of the audit team members. The observers concluded that the audit team members had the necessary expertise and were well-prepared to audit the subject matter in the QA program.

4.4 Examination of the QA Elements

OQA conducted a two-part audit of BSC on June 11 through 20, 2001. The audit team conducted the first part of the audit on June 11 through 15, 2001, at four national laboratories supporting BSC at LBNL, LLNL, LANL, and SNL. The audit team conducted the second part of the audit on June 18 through 20, 2001, at the BSC facility at Las Vegas, Nevada. The audit team identified the following potential deficiencies during the audit.

4.4.1 AP–SIII.1Q, “Scientific Notebooks”

DOE Procedure No. AP-SIII.1Q, “Scientific Notebooks,” Revision 1, Interim Change Notice (ICN) 0, requires that Scientific Notebook (SN) Supplemental Records be referenced to the SN number and that the Supplemental Record display the page of the associated SN. The audit team reviewed SN-LANL-SCI-239 V1 and SN-SNL-SCI-021 V1 and found that the required references between the SNs and the associated Supplemental Records were not maintained. The SNs referred to the Supplemental Records as a “loose-leaf binder,” with no identification of the attachment number to the SN.

The observers agreed with the audit team’s findings in this area.

4.4.2 AP–SIII.4Q, “Development, Review, Online Placement and Maintenance of Individual Reference Information Base Data Items”

DOE Procedure No. AP-SIII.4Q, “Development, Review, Online Placement and Maintenance of Individual Reference Information Base Data Items,” Revision 0, ICN 2, requires that an Online Review Checklist be approved and submitted with the Reference Information Base (RIB) records package. The audit team reviewed RIB packages RIB0090 and RIB0093 and found that the Review Checklists were not approved and were not included in the final records packages.

The observers agreed with the audit team’s findings in this area.

4.4.3 AP–12.1Q, “Control of Measuring and Test Equipment and Calibration Standards”

DOE Procedure No. AP–12.1Q, “Control of Measuring and Test Equipment and Calibration Standards,” Revision 0, ICN 1, requires that Measuring and Test Equipment (M&TE) be tagged, indicating calibration status, and that equipment used be tracked on a master M&TE list. The audit team reviewed selected M&TE at LLNL Corrosion Studies Laboratory and found that M&TE in use was not tagged, indicating calibration status, and was not listed on the master M&TE list.

The observers agreed with the audit team’s findings in this area.

4.4.4 AP-2.21Q, “Quality Determinations and Planning for Scientific, Engineering and Regulatory Compliance”

DOE Procedure No. AP-2.21Q, “Quality Determinations and Planning for Scientific, Engineering and Regulatory Compliance,” Revision 1, ICN 1, requires that a Technical Work Plan be approved and in place before an Analysis Model Report (AMR) is developed. The audit team reviewed AMR ANL-EBS-MD-0049, Revision 00, ICN 01, and found that there was no evidence of a technical review plan approved and in place for this AMR.

The observers agreed with the audit team's findings in this area.

4.4.5 AP-3.10Q, “Analyses and Models”

DOE Procedure No. AP-3.10Q, “Analyses and Models,” Revision 2, ICN 4, requires an evaluation to determine the need to control electronic data in accordance with QARD Supplement V during AMR development. The audit team reviewed documentation associated with AMR ANL-EBS-MD-00033 and found that there was no evaluation nor statement regarding the need to control electronic data in accordance with QARD Supplement V.

The observers agreed with the audit team's findings in this area.

4.4.6 AP-SIII.6Q, “Geophysical Logging Programs for Surface-Based Testing Program Boreholes”

The audit team reviewed DOE Procedure No. AP-SIII.6Q, “Geophysical Logging Programs for Surface-Based Testing Program Boreholes,” Revision 0, and found that the “Process” section does not provide the management processes required to achieve the “Purpose” of the procedure. Specifically, Procedure No. AP-SIII.6Q does not provide for a determination of applicability of the data intended for use. The procedure also does not provide for an identification of applicable portions of the Site Characterization Plan, and Sections III.2.1, “Planning Scientific Investigations,” and III.2.4, “Data Review, Adequacy, and Usage,” of QARD Supplement III.

The observers agreed with the audit team's findings in this area.

5.0 NRC STAFF FINDINGS

The observers determined that OQA Audit BSC-ARC-01-10 was effective in determining the level of compliance of BSC QA activities. The observers agreed with the audit team's conclusion that the OCRWM QA program had been satisfactorily implemented, except for the identified potential deficiencies.

5.1 NRC Audit Observer Inquiries

The observers did not generate any Audit Observer Inquiries (AOIs) during the audit.

5.2 Open NRC AOIs from Previous NRC Observations

The following AOIs remain open from previous DOE audits observed by NRC:

- a) AOI No. M&O-APR-01-02-4, dated February 9, 2001, was written to identify an observer inquiry for ANL-NBS-HS-00032. The AOI states: "The work upon which this model is based (Flint, et al., 1996, "Conceptual and Numerical Model of Infiltration at Yucca Mountain") is unqualified. (See OCRWM QA Audit Report M&O APR-00-04)(p. 9). Was information used to support conclusions made in the Infiltration AMR? If yes, describe how the Flint, et al. (1996) data were qualified and assumptions verified. NRC requests additional information and details. (Refer to U.S. NRC's Observation Audit Report No. OAR-00-04)."
- b) AOI No. M&O-APR-01-01-01, February 2001, was written to identify an observer inquiry for ANL-EBS-MD-000033. Several agreements made at the NRC/DOE Technical Exchange (January 9-12, 2001, Pleasanton, CA) on Evolution of the near Field Environment (EMFE) indicate that new data and analysis will be presented in the "EBS: Physical and Chemical Environment Model AMR (ANL-EBS-MD-000033)," expected to be available in FY 02. The following NRC/DOE agreements point specifically to the FY 02 revision of this AMR: ENFE 2.04; ENFE 2.06; ENFE 2.08; ENFE 2.11; ENFE 2.13, and ENFE 2.18. ENFE 2.05 and ENFE 2.17 also point to this AMR, although they state the information can be provided in other documents as appropriate. During the M&O-APR-01 audit of ANL-EBS-MD-000033, Rev. 01, in Las Vegas, NV (February 20-23, 2001), however, audit team members questioned the usefulness of producing additional revisions of this AMR. If data and analyses required to fulfill NRC/DOE agreements listed above are not presented in a FY 02 revision of the ANL-EBS-MD-000033 AMR, where will this information be presented?" (Refer to U.S. NRC's Observation Audit Report No. QAR-01-03).